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Randomized Controlled Trial Methods Find Exp Clin Pharmacol. 2009 Dec;31(10):655-9.

doi: 10.1358/mf.2009.31.10.1441078.

# Effects of a proprietary Bacillus coagulans preparation on symptoms of diarrhea-predominant irritable bowel syndrome

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## Abstract

Symptoms of irritable bowel syndrome (IBS) have a profound impact on quality of life for many patients and current treatments are sometimes unsatisfactory. This controlled pilot study was conducted to evaluate effects of the proprietary GanedenBC(30) (Bacillus coagulans GBI-30, 6086) probiotic on IBS symptoms, in a randomized, double-blind, placebo-controlled clinical trial including patients with diarrhea-predominant IBS (IBS-D). Patients were randomized to receive either B. coagulans GBI-30, 6086 or placebo once a day for 8 weeks. Patients filled out a quality-of-life questionnaire, and self-assessment diaries were provided to record stool count and consistency, symptom severity, and medication consumption. Of the 61 patients enrolled, six did not meet the inclusion criteria and three were lost to follow-up. Of the remaining 52 patients with IBS-D, the average number of bowel movements per day was significantly reduced for patients treated with B. coagulans GBI-30, 6086 when compared to placebo (P = 0.042). Large variability in baseline scores prevented the assessment of severity scores and quality of life. This small pilot study provides evidence that the proprietary B. coagulans GBI-30, 6086 probiotic is safe and effective for reducing daily bowel movements in patients with IBS-D.

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